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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,388	02/07/2006	Sanyog M. Pendharkar	ETH5084USPCT	6658
27777 7590 11/26/2008 PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			EXAMINER WARE, DEBORAH K	
			ART UNIT 1651	PAPER NUMBER
			MAIL DATE 11/26/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/567,388	<b>Applicant(s)</b> PENDHARKAR ET AL.	
	<b>Examiner</b> DEBBIE K. WARE	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 1-13 are pending and presented for reconsideration on the merits.

#### ***Response to Amendment***

The extension of time, amendment and response filed August 7, 2008, have been received and entered. Please note that there are two separate sets of claims 1-13 and 1-14 in the case, both filed on February 7, 2006. Examiner would like to point out that the set of claims 1-13 are what has been examined and Applicants response of August 7, 2008, has confirmed that these are the claims pending in the case.

#### ***Specification***

The instant case is a 371 of PCT/US04/23765 filed June 23, 2004 and Applicants' update provided in the amendment noted, above, for the instantly filed specification at page 1, line 1 to indicate the 371 priority benefit and the provisional case benefit of priority as well dated August 7, 2003, is hereby acknowledged.

#### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on April 24, 2006, was received. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-13 are rejected under 35 U.S.C. 102(b) as being anticipated by US 2002/0042378, Reich et al, cited on enclosed PTO-1449 Form.

Claims are drawn to a sterile hemostatic composition comprising a continuous liquid phase comprising thrombin and solid phase having polymeric particles and method of making, therefore.

Reich et al teach a hemostatic composition comprising a continuous liquid phase comprising thrombin and solid phase having polymeric particles and method of making, therefore, Note page 3, [0021], all lines wherein a hemoactive composition is defined as having a liquid and solid phase and the solid phase is comprised by the liquid phase. Further a biocompatible polymer is disclosed. Also at page 2, [0012], line 9 thrombin is disclosed as the desirable hemostatic agent. Also the irradiation is disclosed as a conventional sterilization procedure, note the last 4 lines of [0012] at page 2. Therefore, the hemostatic and method of making it are clearly disclosed by the cited reference. Each of the proteins are disclosed as well. The steps of the process of combining and mixing and irradiation are discussed.

The claims are identical to the cited disclosure and are, therefore, considered to be anticipated by the teachings of the cited reference.

### ***Response to Arguments***

Applicant's arguments filed August 7, 2008, have been fully considered but they are not persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., liquid dispersions) are not recited in the rejected claim(s). Although

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the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, the argument that Reich et al never disclose sterilization of the liquid and as such the intermediate composition cannot comprise sterile thrombin is noted. However, at page 5, col. 2, lines 2-4, the composition is disclosed to be sterilized and the composition is disclosed to contain thrombin. Thus, upon sterilization of the composition the thrombin will be sterilized as well because it is contained by the whole composition. The method of preparing the instant composition does not necessarily require sterilization of the liquid either but sterilization of the whole composition, note instant claim 8, of page 12, line 8. Applicants' claims do not omit sterilization of the composition as a whole at least as the claims read now. The arguments are not deemed persuasive and the rejection is sustained.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the previously enclosed PTO-1449 Form and/or PTO-892 Form.

Therefore, the claims are properly rejected.

The remaining references cited on the previously enclosed Forms are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEBBIE K. WARE whose telephone number is (571)272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DKW/

/David M. Naff/

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Deborah K. Ware  
Examiner  
Art Unit 1651

Primary Examiner, Art Unit 1657